September 21, 2022

Meta Systems Co., Ltd
℅ Yang Ho Dong
Manager
Onbix Corporation
#821 Samil Plaza, 14 Dogok-ro 1-gil, Gangnam-gu
Seoul, 06253
SOUTH KOREA

Re: K210475
Trade/Device Name: EQ-M
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX, LQY
Dated: August 16, 2022
Received: August 23, 2022

Dear Yang Ho Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210475

Device Name
EQ-M

Indications for Use *(Describe)*
The EQ-M motorized handpiece can be used to enlarge and prepare root canals, remove gutta-percha points. When connected to Apex locator (EQ-PEX), the EQ-M can be used to measure the length of root canals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
K210475

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

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Date Summary Prepared: Sep 16, 2022

Device Information:

Trade Name(s):	EQ-M
Common/Usual Name:	Dental Endo Motor
Classification Name:	handpiece, direct drive, ac-powered
Regulation Class:	Class 1
Panel:	Dental
Regulation Number:	872.4200
Primary Product Code:	EKX
Additional Product Code:	LQY

Predicate Device Information:

	K number	Device name	Manufacturer
Primary Predicate Device	K112665	Tri Auto mini	J. MORITA MFG. CORP
Reference Device	K170275	Tri Auto ZX2	J. MORITA MFG. CORP

Device Description:

EQ-M is micro motor needed to make canal enlargement for root canal treatment. The battery in the motor handpiece is used as a power source and the rotational power generated by rotating the micro motor is transmitted to the crown gear of the angle head through the bevel gear and shaft. The resulting rotational power is transmitted to the file to rotate the file. When connected to Apex Locator (EQ-PEX), the EQ-M indicates the position of the file tip inside the root canal.

The EQ-PEX is Electronic Apex Locator and accessories to be used to treat patients. It consists of the main body and lip hook, probe cord. The device is used to track the position of the file in the root canal based on the impedance of two different frequencies.

The screen displays measurement information of the root canal length at the current location of the file and displays a number and graph. Stainless steel hand files are intended to be used with the subject device. Lip hook is intended to be placed on the opposite lip of the tooth to be worked on. The file is slowly inserted into the root canal. When the file approaches the apex reference value and alarm will beep and the text apex will appear on the measurement screen.

Indications for Use:
The EQ-M motorized handpiece can be used to enlarge and prepare root canals, remove gutta-percha points. When connected to Apex locator (EQ-PEX), the EQ-M can be used to measure the length of root canals.

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

Summary of the technological characteristics compared to the predicate device
Subject device is substantially equivalent to the predicate device in its technological characteristics stated in the comparison table as attached.

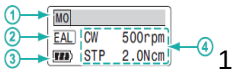
Comparison of Technical characteristics

Features	Subject Device	Primary Predicate Device	Reference Device	Comparison
Product name	EQ-M	Tri Auto mini	Tri Auto ZX2	-
510(k) number	-	K112665	K170275	
Applicant	Meta Systems Co., Ltd.	J. MORITA MFG. CORP.	J. MORITA MFG. CORP.	-
Primary Product Code	EKX	EKX	EKX	Same.
Additional Product Code	LQY	-	LQY	Same
Components	Handpiece, Contra angle, Battery, Battery charger, Power Cord, AC/DC Adapter	Handpiece, Contra angle, Battery, Battery charger, Power Supply Cord	Handpiece, Contra angle, Battery Charger, AC Adapter, Contrary Electrode, File Holder, Probe Cord	Same
Operation with Apex Locator	1. Connect Contra angle 2. File installation 3. Connect the handpiece to the Apex Locator with a Transmission cable (probe cord). 4. The measurement bar shows the location of the file tip. 5. Hook the Contrary Electrode (Lip hook) in the corner of the patient's mouth. 6. Operate the handpiece. 7. If the file tip goes past the Flash bar,	1. Connect Contra angle 2. File installation 3. Connect the handpiece to the Apex Locator with a Transmission cable. 4. The measurement bar shows the location of the file tip. 5. Hook the Contrary Electrode in the corner of the patient's mouth. 6. Operate the handpiece. 7. If the file tip goes past the Flash bar, an alarm will sound	1. Connect Contra angle 2. File installation 3. Connect the probe cord to the motor handpiece. 4. Connect the file holder and the lip hook to the probe cord respectively. 5. The measurement bar shows the location of the file tip. 6. Hook the Contrary Electrode in the corner of the patient's mouth. 7. Operate the handpiece. 8. If the file tip goes	Same

	an alarm will sound and the backlight will blink on an off.	and the backlight will blink on an off.	past the Flash bar, an alarm will sound and the backlight will blink on an off.	
Comparison Statement	The EQ-M motorized handpiece can be used to enlarge and prepare root canals, remove gutta-percha points. When connected to Apex locator, the EQ-M can be used to measure the length of root canals.	The Tri Auto mini motorized handpiece can be used to enlarge and prepare root canals, remove gutta-percha points, and for professional tooth cleaning. When connected to Apex locator, the Tri Auto mini can be used to measure the length of root canals.	The Tri Auto ZX2 device is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.	Same
Principle of operation	The battery in the motor handpiece is used as a power source and the rotational power generated by rotating the micro motor is transmitted to the crown gear of the angle head through the bevel gear and shaft. The resulting rotational power is transmitted to the file (tip) to rotate the file (tip). When connected to Apex Locator (EQ-PEX), the EQ-M indicates the position of the file tip inside the root canal.	The Tri Auto mini is an Battery- driven handpiece with a motor, equipped with the chuck for holding rotary instrument such as a dental file and a reamer. Tri Auto mini can be used for enlargement and preparation of root canals. When connected to Apex Locator, the Tri Auto mini indicates the position of the file tip inside the root canal.	Electrical motor drives the rotating of file equipped on the rotating to accomplish it's indication for use. And the software control the parameter and method of rotating.	Same
Intended use	- Canal enlargement - Root canal length measurement (When connected to Apex Locator)	- Canal enlargement - Root canal length measurement (When connected to Apex Locator)	- Canal enlargement - Root canal length measurement	Same
Indication for use	The EQ-M motorized	The Tri Auto mini motorized	The Tri Auto ZX2 device is a cordless	Same

	handpiece can be used to enlarge and prepare root canals, remove gutta-percha points. When connected to Apex locator (EQ-PEX), the EQ-M can be used to measure the length of root canals.	handpiece can be used to enlarge and prepare root canals, remove gutta-percha points, and for professional tooth cleaning. When connected to Apex locator, the Tri Auto mini can be used to measure the length of root canals.	endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.	
Device Description	EQ-M is micro motor needed to make canal enlargement for root canal treatment. The battery in the motor handpiece is used as a power source and the rotational power generated by rotating the micro motor is transmitted to the crown gear of the angle head through the bevel gear and shaft. The resulting rotational power is transmitted to the file to rotate the file. When connected to Apex Locator (EQ-PEX), the EQ-M indicates the position of the file tip inside the root canal. The EQ-PEX is Electronic Apex Locator and accessories to be used to treat patients. It consists of the main body and lip hook, probe	The Tri Auto mini is an battery- driven handpiece with a motor, equipped with the chuck for holding rotary instrument such as a dental file and a reamer. Tri Auto mini can be used for enlargement and preparation of root canals. When connected to Apex Locator (Which is not included in this application), the Tri Auto mini indicates the position of the file tip inside the root canal.	The Tri Auto ZX2 is a battery-driven handpiece with a motor, equipped with a chuck for holding rotary instruments such as a dental file and reamer. The Tri Auto ZX2 can be used for cutting and grinding teeth by transferring rotary movement to a rotary instrument attached to the head. Cutting and grinding of teeth can be done depending on the situation by switching (reversing) the rotation direction. Rotation speed is accelerated or decelerated according to the user's preference, rotation control based on torque detection, or set timing. These controls enable the	Same

	cord. The device is used to track the position of the file in the root canal based on the impedance of two different frequencies. The screen displays measurement information of the root canal length at the current location of the file and displays a number and graph. Stainless steel hand files are intended to be used with the subject device. Lip hook is intended to be placed on the opposite lip of the tooth to be worked on. The file is slowly inserted into the root canal. When the file approaches the apex reference value an alarm will beep and the text apex will appear on the measurement screen.		cutting, grinding, enlargement, and preparation of root canals. Moreover, the Tri Auto ZX2 can be used for the removal of extraneous materials such as gutta-percha points, and for professional mechanical tooth cleaning. In addition, the Tri Auto ZX2 can be used as an apex locator, and the measured value can be used for rotation control.	
Usage	Prescription Use	Prescription Use	Prescription Use	Same
Technical Specification				
Energy used and/or delivered	Li-ion battery (DC 3.7V)	Li-ion battery (DC 3.7V)	Li-ion battery (DC 3.7V)	Same
Exterior Design	28 mm x 27.2 mm x 154.4mm Charger: 80 mm x 83 mm x 89.5 mm	18 mm x 18 mm x 165 mm Charger: 85 mm x 108 mm x 68 mm	30 mm x 30mm x 200 mm Charger: 85 mm x 85mm x 75 mm	Different (1)
Performance 1 - canal enlargement	100-1,000rpm, 4Ncm	50-1,000rpm, 4Ncm	100-1,000rpm, 4Ncm	Same
Performance 2 - apex locator	Accuracy of the root apex locator function: -0.5mm to +0.5mm from Apex position	-	Accuracy of the root apex locator function : -1.5mm to +0.5mm for Apex position.	Different (2)

Setting Mode	EAL: When the Apex Locator and EQ-M are connected properly. CW: The motor rotates clockwise. CCW: The motor rotates counterclockwise. RCP: The motor alternates between clockwise and counterclockwise rotation. ART: The motor rotates clockwise while changing its speed.	Linked function: These functions are available only when connected to the Electronic Apex Locator. Fwd: The motor rotates clockwise. Rev: The motor rotates counterclockwise. Torque Reverse: nine torque reverse settings Auto controls: Auto torque Reverse/ Auto torque slowdown	EMR Mode: This mode is for canal measurement. CW Mode: The motor rotates clockwise. OGP Mode: Optimum Glide Path function is used for canal negotiation and making the glide path.	Different (3)
Display setting	 1. Memory number 2. EQ-M and Apex Locator connection 3. Battery Power 4. Motor operation information 1) CW: Rotation Direction 2) RPM: Motor Speed 3) Ncm: Torque 4) STP: The motor stops when it reaches the set torque limit.	 1. Memory number 2. Rotation Direction 3. Battery Power 4. Speed Setting 5. Torque Reverse Setting	 1. Memory Number 2. Battery Power 3. Operation Mode 4. Speed Setting 5. Torque Limit Setting	Same.
Spray nozzle	Spray nozzle	-	Spray nozzle	Same
Sterility	Contra angle (Lip hook are not attached)	Contra angle (File holder and Contrary electrode are not attached)	File holder, contrary electrode, and contra angle are autoclavable.	Same
Applied Standards				
Standards met	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 62304 ISO 14971 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 17665-1 ISO 17665-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-1-6 ISO 14971 ISO 10993-1 ISO 10993-5 ISO 10993-12 ISO 17664	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 62304 IEC 62366 ISO 14971 ISO 10993-1 ISO 10993-5 ISO 10993-12 ISO 15223-1	Different (4)

	ISO 11737-1 IEC 62366-1 IEC 62133-2 IEC 80601-2-60 ISO 14457 ISO 1797-1 ISO 7405 ISO 15223-1		ISO 17664	
Materials	Materials conform to ISO 10993.	Materials conform to ISO 10993.	Materials conform to ISO 10993.	Same
Compatibility with environment and other devices.	Conform to IEC 60601-1-2	Conform to IEC 60601-1-2	Conform to IEC 60601-1-2	Same
Electrical Safety	Conform to IEC 60601-1	Conform to IEC 60601-1	Conform to IEC 60601-1	Same
Mechanical Safety	Conform to IEC 60601-1	Conform to IEC 60601-1	Conform to IEC 60601-1	Same
Thermal Safety	Conform to IEC 60601-1	Conform to IEC 60601-1	Conform to IEC 60601-1	Same
Radiation safety	Conform to IEC 60601-1-2	Conform to IEC 60601-1-2	Conform to IEC 60601-1-2	Same

Justifications for differences between proposed device and the predicate device are shown as below:
Different (1): The exterior design of the EQ-M compared to the Tri Auto mini has slightly changed for design. However, the structures of both devices which include the contra angle that connects and rotates the files are substantially equivalent. Moreover, the principle of controlling the rotation by measurement result, load value, setting etc. is also substantially equivalent. The structure to which the probe code of the Apex locator is connected is also substantially equivalent.
Different (2): The accuracy of the root apex locator is within the accuracy of the Tri Auto ZX II reference predicate device, thus substantially the equivalent.
Different (3): The names of the modes are different, but the functions are substantially identical.
Different (4): The standards applied to the EQ-M include those of predicate devices, so there is no effect on safety and effectiveness.

Non-Clinical Study performance

To be in compliance with electromagnetic safety and compatibility, appropriate study has been applied to the subject device in accordance with the following standard

ISO 14971:2007	Medical devices Application of risk management to medical devices
IEC 60601-1:2005 + A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Part1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 60601-1-6: 2010/AMD1:2013	Medical electrical equipment – Part 1-6: General requirements for safety and essential performance – Collateral standard: Usability
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 62304:2006+A1:2015	Medical device software – Software life cycle processes
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 7010:2019	Graphical symbols – Safety colors and safety signs – Registered safety signs
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 11737-1:2018	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
IEC 80601-2-60:2019	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment
ISO 14457:2017	Dentistry - handpieces and motors
ISO 1797:2017	Dentistry – Shanks for rotary and oscillating instruments
ISO 7405:2018	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
FDA Reprocessing Guidance	Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
FDA Software Guidance	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Conclusion

Subject device has the same device characteristics as the predicate device, based on the information provided in this summary we conclude that subject device is substantially equivalent to the predicate device.